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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,559	11/21/2000	Boris V. Smolyarov	01752810	1717

26565 7590 12/09/2009
MAYER BROWN LLP
P.O. BOX 2828
CHICAGO, IL 60690

EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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12/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No. 09/717,559	Applicant(s) SMOLYAROV ET AL.	
	Examiner Manuel A. Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/29/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by **Brignola (US 4331146)**.

Brignola shows in figures 14-15, 38-39 and 44-45, a removable cap generally distal to the distal end orifice, the cap further including a cap distal face and a cap proximal face, and an injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-27 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Landau (US 6264629)** in view of **Landau, et al. (US 6132395)**, and in further view of **Brignola (US 4331146)**. The Landau Patent does not disclose a piston at the distal end of the orifice and a latch. However, the use of pistons and

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latches at the distal end of an infusion system are conventional in the art evidenced by the teachings Landau, et al. The Landau, et al., Patent demonstrates the conventionality of using an orifice shield (figures 17A and 17b), a piston (figure 1), and a latch (figures 12A and 17b) to prevent the injection of an infusion system. Accordingly, the modification of the Landau infusion system with the above enhancements would have been considered an obvious design choice. In relation to claim 33, the cited steps are considered inherent to the apparatuses of the Landau and Landau, et al., Patents, and accordingly would have been considered obvious.

Finally, in response to the amendments to the claims, the Brignola patent discloses a removable cap generally distal to the distal end orifice, the cap further including a cap distal face and a cap proximal face, and an injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice. Based on the above observations, for a person of ordinary skill in the art, modifying the apparatus disclosed by Landau or Landau, et al. with a removable cap and an injection prevention component, as taught by Brignola, would have been considered obvious in view of the proven conventionality of these enhancements and the resulting enhanced efficiency of the injector assembly.

Response to Arguments

Applicant's arguments filed on 02/19/2009 have been fully considered but they are not persuasive. Applicant's arguments are based primarily on an amendment to the preamble. The examiner notes for the record that a preamble may be only limiting if it **"gives life and meaning"** to the invention. In the present circumstance, the term

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“needle-free” is not defined in the specification. Moreover, the term “multi-use” is also not defined in the specification and is not structurally limiting. Accordingly, the examiner concludes that the amendment to the preamble does not give life and meaning to the pending claims, and therefore, the pending rejections will be maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
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MM